NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA UK LIMITED,

Plaintiffs, : Civ. Action No.: 15-3384 (FLW)(DEA)

v. : MEMORANDUM OPINION AND : ORDER

MYLAN PHARMACEUTICALS INC.,

Defendant.

WOLFSON, United States District Judge

Plaintiffs, Takeda GmbH, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited (collectively, "Plaintiffs"), bring this Hatch-Waxman Act patent infringement suit against Defendant Mylan Pharmaceuticals Inc. ("Defendant"), alleging that Defendant infringed U.S. Patent Nos. 5,712,298, 8,536,206, 8,604,064, and 8,618,142 (collectively, the "Patents-in-Suit") pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Abbreviated New Drug Application 208257 seeking to market generic versions of Plaintiffs' product, Dalisresp, and that Defendant will infringe the Patents-in-Suit pursuant to 35 U.S.C. § 271(a), (b), and (c). Defendant moves to dismiss Plaintiffs' claims under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction. Plaintiffs oppose the motion.

Defendant asserts that it lacks any claim-related or jurisdiction-conferring contacts with New Jersey. Br. in Supp. of Def.'s Mot. To Dismiss for Lack of Personal Jurisdiction ("Def.'s Supp. Br.") 2-3. Plaintiffs counter that Defendant is subject to this Court's personal jurisdiction

because 1) Defendant's compliance with New Jersey's foreign corporation licensing and registration statute (the "Registration Statute"), N.J.S.A §§ 14A:4-1 to -6, constitutes consent to this Court's jurisdiction, 2) Defendant's contacts with New Jersey are so systematic and continuous as to render it "at home" in the state, sufficing to confer general jurisdiction, and 3) Defendant's mailing of its "paragraph IV" ANDA notification to New Jersey, or alternatively Defendant's intent to market and distribute its generic products in New Jersey in the future, are sufficient to confer specific jurisdiction. Pls.' Opp'n to Def.'s Mot. To Dismiss for Lack of Personal Jurisdiction ("Pls. Opp'n Br.") 1-2.

Although Defendant is a Virginia corporation with its principle place of business in Morgantown, West Virginia, it is currently registered to conduct business in New Jersey and maintains a registered agent to accept service of process, pursuant to the Registration Statute. *See* Decl. of Frank Mullery ("Mullery Decl.") ¶ 4; Decl. of Tracy C. Allen ("Allen Decl.") Ex. B, 1. Defendant frequently litigates in this district, having been a party to 41 patent infringement cases since 2010, the majority of which are related to ANDAs filed by Defendant. See Allen Decl. Ex E. Approximately 2% of Defendant's total net U.S. revenue for 2014, an amount exceeding \$51 million, was derived from sales in New Jersey. See Mullery Decl. at ¶ 8. Defendant has also collaborated with its parent company, Mylan Inc., on at least one clinical trial in New Jersey, see

¹ Plaintiffs appear to argue that Defendant's prior litigation activity and its admission of personal jurisdiction in other cases in this district extend consent to jurisdiction in this case. *See* Pls. Opp'n Br. at 21. However, the Court agrees with its sister court's finding in *Otsuka Pharm. Co. v. Mylan Inc.* that admission of jurisdiction in one case does not extend a blanket consent to personal jurisdiction in all other cases brought in that district. 106 F. Supp. 3d 456, 467 n 10 (D.N.J. 2015) (citing *Mallinckrodt Med., Inc. v. Sonus Pharms.*, 989 F. Supp. 265, 271 (D.D.C. 1998)); *see also Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro in Amministrazione Straordinaria*, 937 F.2d 44, 50 n 5 (2d Cir. 1991) ("a party's consent to jurisdiction in one case, however, extends to that case alone").

Allen Decl. Ex. J, and employs New Jersey residents.² *See* Mullery Decl. at ¶ 7. Defendant argues that merely complying with the Registration Statute coupled with a modicum of business in New Jersey is an insufficient basis to find that it consented to personal jurisdiction in the state. Def.'s Supp. Br. at 2. Additionally, Defendant also contends that specific jurisdiction is inappropriate because Plaintiffs' cause of action does not arise from any of Defendant's activities in New Jersey. Reply Br. in Further Supp. of Def.'s Mot. To Dismiss for Lack of Personal Jurisdiction ("Def.'s Reply Br.") 7-10.

Recently, in a number of analogous cases in which Defendant is a party, Defendant also moved to dismiss for lack of personal jurisdiction for nearly identical reasons; other courts in this district have denied Defendant's motion on the basis that registration under the Registration Statute, coupled with engaging in a substantial amount of business in New Jersey, constitutes consent to jurisdiction in New Jersey. *See Otsuka*, 106 F. Supp. 3d at 470 ("... Mylan Pharma consented to the Court's jurisdiction by registering to do business in New Jersey, by appointing an in-state agent for service of process in New Jersey, and by actually engaging in a substantial

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² Defendant asserts that taken together, these contacts with New Jersey fall short of the systematic and continuous contacts necessary to confer general jurisdiction. Def.'s Supp. Br. at 2. Indeed, such contacts are not "so pervasive that they may substitute for its place of incorporation or principal place of business," rendering Defendant "at home" in New Jersey and subject to general jurisdiction. *In re Asbestos Prods. Liability Litig.* (No. VI), 2014 WL 5394310, at *3 (E.D.Pa. Oct. 23, 2014) ("an 'exceptional case' authorizing general jurisdiction is one in which the defendant's forum contacts are so pervasive that they may substitute for its place of incorporation or principal place of business") (citing *Monkton Ins. Servs., Ltd. v. Ritter*, 768 F.3d 429, 432 (5th Cir. 2014) (it is "incredibly difficult to establish general jurisdiction in a forum other than the place of incorporation or principal place of business")); *see also Otsuka*, 106 F. Supp. 3d at 466 (not ruling on general jurisdiction, but observing that "Mylan Defendants' fractional revenue generation in New Jersey, 'frequent' litigation in this District, in addition to the physical presence of various Mylan subsidiaries in this State . . . do not appear the functional equivalent of incorporation or principal place of business, nor do they unequivocally demonstrate the requisite operations of the Mylan Defendants within this State") (internal citations omitted).

amount of business in this State."); Boehringer Ingelheim Pharma GmbH & Co. v. Teva Pharmaceuticals USA, Inc., Civ. No. 14-7811, Dkt. 76 (D.N.J. July 16, 2017); Janssen Products, L.P. v. Mylan Pharmaceuticals Inc., Civ. No. 14-4550, Dkt. 62 (D.N.J. July 8, 2015). However, decisions on nearly identical motions in the district of Delaware are divided as to whether compliance with Delaware's corporate registration statute constitutes consent to jurisdiction in Delaware. ³ See AstraZeneca AB v. Mylan Pharm., Inc., 72 F. Supp. 3d 549, 559 (D. Del. 2014) motion to certify appeal granted sub nom AstraZeneca AB v. Aurobindo Pharma Ltd., Civ. No 14-664, 2014 WL 7533913 (D. Del. Dec. 17, 2014) (invalidating consent-by-registration); but see Acorda Therapeutics, Inc. v. Mylan Pharm. Inc., 78 F. Supp. 3d 572, 592 (D. Del. 2015) (finding Defendant subject to jurisdiction due to consent-by-registration); Novartis Pharm. Corp. v. Mylan Inc., Civ. No. 4-777, 2015 WL 1246285, at *4 (D. Del. Mar. 16, 2015) (finding Defendant subject to jurisdiction due to consent-by-registration); Forest Labs., Inc. v. Amneal Pharm. LLC, Civ No. 14-508, 2015 WL 880599, at *11 (D. Del. Feb. 26, 2015) ("the scope of Delaware's corporate registration statute is such that when a foreign corporation complies with its terms, including appointing an agent for service of process in the State, this amounts to the kind of actual, express consent to personal jurisdiction"). One of these decisions, AstraZeneca AB, is presently on appeal

³ The Court notes that where district courts in Delaware did not find consent-by-registration, they denied Defendant's motion to dismiss on the grounds that "the act of filing an ANDA and the paragraph IV notification provide[d] sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis." *AstraZeneca AB*, 72 F. Supp. 3d at 557; *see also Acorda*, 78 F. Supp. 3d at 592. A court in the Southern District of Indiana, addressing nearly identical filings from Defendant, also reached the same conclusion. *See Eli Lilly & Co. v. Mylan Pharm., Inc.*, 96 F. Supp. 3d 824, 834 (S.D.Ind. 2015).

before the Court of Appeals for the Federal Circuit. AstraZeneca AB v. Mylan Pharm., Inc., Civ. No 15-1460 (Fed. Cir. Docketed May 17, 2015).

Generally, a district court may exert personal jurisdiction over a nonresident of the state in which the court sits only if authorized by both the forum state's long-arm statute and the Due Process Clause of the United States Constitution. *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1016 (Fed. Cir. 2009). In this district, because New Jersey's long-arm statute permits jurisdiction to the full extent of the Due Process Clause, *IMO Indus., Inc. v. Kiekert AG*, 155 F.3d 254, 259 (3d Cir. 1998), this inquiry is reduced to a single question of "whether the exercise of jurisdiction comports with due process." *Autogenomics*, 566 F.3d at 1017 (internal citations omitted). Due process demands that a defendant have "certain minimum contacts with [the State] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice." *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014) (quoting *Goodyear Dunlop Tires Operations*, *S.A. v. Brown*, 131 S. Ct. 2846, 2853 (2011)).

Jurisdiction over a foreign defendant is based on two categories of contacts with the forum state: general and specific. *Daimler*, 134 S. Ct. at 754. General jurisdiction applies where a foreign defendant's contacts with the forum state are "so 'continuous and systematic' as to render [it] essentially at home in the forum State." *Daimler*, 134 S. Ct. at 749 (internal citations omitted).

⁴ "Federal Circuit law unquestionably governs the key disputed issue, namely, whether due process would be offended in the event the Court exercised personal jurisdictional over the Mylan Defendants, the 'out-of-state accused infringer[s]." *Otsuka*, 106 F. Supp. 3d at 462 (quoting *Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1230 (Fed. Cir. 2010)) (citing additionally *Hildebrand v. Steck Mfg. Co., Inc.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002) ("We apply Federal Circuit law to determine whether the district court properly exercised personal jurisdiction over out-of-state defendants in patent infringement cases.")).

Specific jurisdiction, on the other hand, applies when the suit at issue arises out of the foreign defendant's contacts with the forum state. *Daimler*, 134 S. Ct. at 754. Additionally, a court may exercise general jurisdiction over a foreign defendant that consents to such jurisdiction. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 473 n 14 (1985) ("personal jurisdiction requirement is a waivable right").

In the first half of the twentieth century, the Supreme Court ruled in a number of cases that a corporation's appointment of an agent for service of process in compliance with a state's corporate registration statute, under certain circumstances, constituted consent to personal jurisdiction in that state. *See Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 175 (1939) (finding a foreign corporation waived its right to contest venue in federal court in New York by complying with the state's corporate registration statute); *Louisville & Nashville Railroad Co. v. Chatters*, 279 U.S. 320, 323-24 (1929) (finding a foreign corporation consented to personal jurisdiction in Louisana by appointing a service agent pursuant to the state's corporate registration statute); *Pa. Fire Ins. Co. of Phila. v. Gold Issue Mining & Milling Co.*, 243 U.S. 93, 95 (1917) (finding the same under Missouri corporate registration statute).

Presently, there is a circuit split as to whether such consent-by-registration is still a viable basis for personal jurisdiction, or whether it has been subsumed by the "minimum-contacts" analysis subsequently introduced in *International Shoe Co. v. State of Washington, Office of Unemployment Compensation & Placement*, 326 U.S. 310 (1945). *Compare Holloway v. Wright & Morrissey, Inc.*, 739 F.2d 695, 697 (1st Cir. 1984) ("It is well-settled that a corporation that authorizes an agent to receive service of process in compliance with the requirements of a state statute, consents to the exercise of personal jurisdiction . . ."); *Bane v. Netlink, Inc.*, 925 F.2d 637, 640 (3d Cir. 1991) ("We need not decide whether authorization to do business in Pennsylvania is

a 'continuous and systematic' contact with the Commonwealth . . . because such registration by a foreign corporation carries with it consent to be sued in Pennsylvania courts."); Knowlton v. Allied Van Lines, Inc., 900 F.2d 1196, 1200 (8th Cir. 1990) ("We conclude that appointment of an agent for service of process under [the Minnesota statute] gives consent to the jurisdiction of Minnesota courts for any cause of action, whether or not arising out of activities within the state. Such consent is a valid basis of personal jurisdiction, and resort to minimum-contacts or due-process analysis to justify . . . jurisdiction is unnecessary."); King v. Am. Family Mut. Ins. Co., 632 F.3d 570, 574 (9th Cir. 2011) ("the appointment of an agent for service of process will subject a foreign insurer to general personal jurisdiction in the forum if the governing state statute so provides"); with Ratliff v. Cooper Labs., Inc., 444 F.2d 745, 748 (4th Cir. 1971) ("The principles of due process require a firmer foundation than mere compliance with state domestication statutes."); Wenche Siemer v. Learjet Acquisition Corp., 966 F.2d 179, 183 (5th Cir. 1992) ("Not only does the mere act of registering an agent not create [defendant's] general business presence in Texas, it also does not act as consent to be hauled into Texas courts on any dispute with any party anywhere concerning any matter."); Wilson v. Humphreys (Cayman), Ltd., 916 F.2d 1239, 1245 (7th Cir. 1990) ("Registering to do business is a necessary precursor to engaging in business activities in the forum state. However, it cannot satisfy . . . standing alone . . . the demands of due process."). There is, as yet, no Federal Circuit precedent as to the viability of consent-by-registration, and the Supreme Court has never explicitly overruled those cases establishing consent-by-registration.

Compounding the uncertainty of the applicability of consent-by-registration in this case, Defendant contends that even if consent-by-registration was not repudiated by *International Shoe*, it has been recently repudiated by *Daimler*. In *Daimler*, the Supreme Court restricted general personal jurisdiction over a foreign corporation to those forums in which it was "at home," *i.e.*

"the place of incorporation and principal place of business." *Daimler*, 134 S. Ct. at 760 (internal citations omitted). Additionally, in certain exceptional cases, "a corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home in that State." *Daimler*, 134 S. Ct. at 761 n 19. This is a departure from the "unacceptably grasping" general jurisdiction analysis previously applied by lower courts, which scrutinized whether a corporation "engag[ed] in a substantial, continuous, and systematic course of business" in the forum state. *Daimler*, 134 S. Ct. at 761.

The *AstraZeneca AB* court reasoned that applying jurisdiction to corporations for merely complying with the forum state's corporate registration statute fundamentally contradicts the due process concerns of fair play and substantial justice raised in *Daimler*. *AstraZeneca AB*, 72 F. Supp. 3d at 556. As that court explained, "[i]n holding that 'continuous and systematic contacts' alone are insufficient to establish general jurisdiction, the Supreme Court rejected the idea that a company could be haled into court merely for 'doing business' in a state." *AstraZeneca AB*, 72 F. Supp. 3d at 556 (citing *Daimler*, 134 S. Ct. at 761-62).

On the other hand, those courts that affirmed the application of consent-by-registration to Defendant, distinguished cases involving consent to jurisdiction from *Daimler*, which focused on general jurisdiction. *Acorda*, 78 F. Supp. 3d at 589; *Otsuka*, 106 F. Supp. 3d at 468. Indeed, "*Daimler* in its entirety contains but one fleeting reference to the concept of jurisdiction by consent, and this limited reference served only to distinguish between traditional 'consensual' jurisdiction and the 'non-consensual bases for jurisdiction' addressed in the decision, rather than to cast any doubt on the continued vitality of consent-based jurisdiction." *Otsuka*, 106 F. Supp. 3d at 468 (referencing this sentence from *Daimler*: "[The Court's] 1952 decision in *Perkins v. Benguet Consol. Mining Co.*[, 342 U.S. 437 (1952),] remains the textbook case of general jurisdiction

appropriately exercised over a foreign corporation that has **not consented** to suit in the forum." 134 S. Ct. at 755-56 (emphasis added)) (quoting *Acorda*, 78 F. Supp. 3d at 589). According to these courts, *Daimler* solely restricted general jurisdiction and had no bearing on previous Supreme Court decisions involving consent to jurisdiction, or specifically consent-by-registration.

Additionally, although it is widely agreed that with *Daimler*, the Supreme Court sought to increase the predictability of personal jurisdiction to allow defendants "to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit," Daimler, 134 S. Ct. at 762 (internal citations omitted), courts fundamentally disagree as to whether the consent-by-registration doctrine impairs predictability of jurisdiction. See Acorda, 78 F. Supp. 3d at 591; AstraZeneca AB, 72 F. Supp. 3d at 556. The Acorda court explained that the predictability problem outlined in *Daimler* only arises when corporations must determine their jurisdiction based on the imprecise analysis of whether their contacts with the forum state are sufficiently "continuous and systematic." Acorda, 78 F. Supp. 3d at 591. "When, instead, the basis for jurisdiction is the voluntary compliance with a state's registration statute, which has long and unambiguously been interpreted as constituting consent to general jurisdiction in that state's courts, the corporation can have no uncertainty as to the jurisdictional consequences of its actions." Acorda, 78 F. Supp. 3d at 591. On the other hand, as the AstraZeneca AB court highlighted, limiting jurisdiction to just two locations, the corporation's place of incorporation and its principal place of business, with limited exceptions, would certainly be a simple and predictable rule for defendant corporations to apply. See AstraZeneca AB, 72 F. Supp. 3d at 556.

The current viability of consent-by-registration is a matter presently on appeal before the Federal Circuit in the matter of *AstraZeneca AB*, Civ. No 15-1460. Additionally, at issue in that appeal is the question of whether filing an ANDA and mailing a "paragraph IV" notification to a

plaintiff in the forum state, pursuant to 21 U.S.C.A. § 355(j), provides a basis for specific jurisdiction. *Id.* Plaintiffs raise identical issues here.

The Federal Circuit applies a three-prong test in determining specific jurisdiction: whether "(1) the defendant purposefully directed its activities at residents of the forum; (2) the claim arises out of or relates to those activities, and (3) assertion of personal jurisdiction is reasonable and fair." *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1332 (Fed. Cir. 2008) (internal citations omitted). Those courts that have reached the issue of specific jurisdiction in their analysis of Defendant's nearly identical motions have found that filing an ANDA and mailing a paragraph IV notification to the forum state is an act directed at the forum state, which gives rise to the plaintiff's cause of action under the Hatch-Waxman Act, and therefore confers specific jurisdiction over the defendant. *See Acorda*, 78 F. Supp. 3d at 592; *AstraZeneca AB*, 72 F. Supp. 3d at 557; *Eli Lilly*, 96 F. Supp. 3d at 834. Here, Defendant likewise sent its paragraph IV notification to Plaintiffs in the forum state, New Jersey, thus triggering the forty-five day count-down under the Hatch-Waxman Act, 21 U.S.C.A. § 355(c)(3)(C), for Plaintiffs to file a lawsuit. *See* Allen Decl. Ex. A. As the *AstraZeneca AB* court explained,

Mylan argues its activities are not purposefully directed at the state of Delaware, where [plaintiff] is organized. Mylan's argument, however, creates the untenable position that its conduct is not directed to any jurisdiction. The Federal Circuit in *Zeneca* eliminated the possibility that Maryland (the location of the FDA and where ANDAs are filed) could exercise specific jurisdiction over ANDA filers, in order to avoid creating a "supercourt" with jurisdiction in all cases. Judge Rader's concurring opinion stated that "Mylan's contacts are not actually with the state of Maryland at all. Rather Mylan's contacts involve the federal government whose office for receipt of ANDAs happens to be within that state." The court finds that the only possible alternative forum is the state of residence for the [plaintiff] patent holder.

AstraZeneca AB, 72 F. Supp. 3d at 558-59 (quoting Zeneca Ltd. v. Mylan Pharm., Inc., 173 F.3d 829, 832, 835 (Fed. Cir. 1999)). The Acorda court took the AstraZeneca AB court's analysis one

step further and found that the absence of mailing a paragraph IV notification into the forum state does not eliminate the possibility of the exercise of specific jurisdiction, where the plaintiff was incorporated in the forum state and thus the "injury" resulting from the ANDA submission was felt in that state. *Acorda*, 78 F. Supp. 3d at 596.⁵

Plaintiffs expand this reasoning further, arguing that an ANDA-based cause of action necessarily involves the defendant's anticipated future patent infringement through the sale of infringing products. Pls. Opp'n Br. at 27-28. Thus, Plaintiffs assert that the cause of action in this litigation arises from Defendant's expected sales of infringing products in New Jersey. Id. Defendant protests that such a broad interpretation would allow plaintiffs to bring Hatch-Waxman Act patent infringement claims in any of the fifty states, encouraging forum shopping. Def.'s Supp. Br. at 21. Moreover, Defendant argues that based on a plain reading of the statute,⁶ Plaintiffs' action arises out of Defendant's filing of the ANDA with the FDA in Maryland, rather than with the mailing of the paragraph IV notification to New Jersey or anticipated future sales of infringing products. Id. at 20. Cognizant that, as discussed by the AstraZeneca AB court, the Federal circuit has eliminated Maryland as a "supercourt" for ANDA cases, see AstraZeneca AB, 72 F. Supp. 3d at 558-59 (citing Zeneca, 173 F.3d at 832), Defendant appears to suggest that West Virginia, where the ANDA was drafted, is therefore the only forum state which might claim specific jurisdiction over this litigation. Id. Similar arguments are squarely before the Federal Circuit. See AstraZeneca AB, Civ. No 15-1460.

⁵ The Court notes that unlike the plaintiffs in Acorda, none of Plaintiffs here are incorporated in New Jersey. Compl. ¶¶ 3-5.

⁶ 35 U.S.C. § 271(e)(2)(A) provides: "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]"

Given the present uncertainty of the law and the Federal Circuit's forthcoming decision on these issues, ⁷ it is in the interests of judicial economy to stay this case pending the Federal Circuit's ruling in *AstraZeneca AB*, Civ. No 15-1460. Moreover, no party has indicated that it will be unduly prejudiced by a stay pending the Federal Circuit's decision, and this Court sees no reason why any party should be unduly prejudiced by such a stay. Accordingly, and the Court having reviewed the parties' submissions in connection with the motion pursuant to Fed. R. Civ. P. 78, for the reasons set forth herein, and for good cause shown,

IT IS on this 12th day of January, 2016,

ORDERED, that Defendant's motion to dismiss is administratively terminated; it is

FURTHER ORDERED that this matter will be **STAYED** pending the outcome of *AstraZeneca AB*, Civ. No 15-1460; it is

FURTHER ORDERED that any party to this litigation may move to lift this stay if their rights in this matter are substantively effected by the pendency of the Federal Circuit's decision.

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge

⁷ The Federal Circuit heard oral argument in *AstraZeneca AB*, Civ. No 15-1460, on January 4, 2016.